

REMARKS

Favorable consideration and allowance are respectfully request for claims 1-9 and 13-19. The Examiner is thanked for the careful consideration of this case and the indication that the § 112 and § 102 rejections are withdrawn is acknowledged with appreciation.

The rejection of claims 1-9 and 13-19 under 35 U.S.C. § 103(a) as obvious over Richardson et al., (WO 96/21437) in view of Gordon et al., (WO) 00/64420 is respectfully traversed.

The claims of the present application are directed to methods of suppressing abnormal prion proteins. The claimed methods require administering an essential amino acid having a branched side chain. For instance, claim 1 below is representative:

A method for suppressing proliferation of abnormal prion proteins, comprising systemically, orally, intracerebrally or intraspinally administering to a patient in need thereof an essential amino acid having a branched side chain.

The Richardson reference describes administering “a meal enriched with large neutral amino acids” to treat abnormal movement disorders including those disorders which are secondary to treatment with neuroleptics and those which manifest themselves as part of a primary neurological disorder or disease (see the abstract). As noted in the Office Action, Richardson is silent as to suppressing the proliferation of abnormal prion proteins. Indeed, the reference

provides no indication that a branched chain amino acid might be operative to suppress the proliferation of abnormal prion proteins.

The Gordon reference is offered as making up for the failure of Richardson to describe the presence of prion proteins, as well as the diseases scrapie, bovine spongiform encephalopathy, and Gerstmann-Straussler-Scheinker syndrome. The Office Action asserts that because Gordon teaches that these diseases are associated with the appearance of protease-resistant prion proteins in the central nervous system, it would be reasonable to treat these diseases with the treatment of Richardson.

However, all Gordon adds is the presence of prion proteins in certain neurodegenerative diseases. Neither of the references, either alone, or in the proposed combination, teaches or suggests the presently claimed methods of suppressing the proliferation of abnormal prion proteins through the claimed administration of certain amino acids to a patient who is in need of this therapy. As stated previously, in the case of *Perricone v. Medicis Pharmaceutical*, 77 USPQ2d 1321 (Fed. Cir. 2005), the court explained that in determining patentability the issue is not whether a prior art treatment would be effective to achieve the claimed result, instead the question is whether the prior art describes the claimed treatment.

Furthermore, Richardson does not teach suppressing abnormal prion proteins by systemically, orally, intracerebrally or intraspinally administering of an essential amino acid having branched side chain, such as leucine, isoleucine,

valine and mixture thereof. Instead, Richardson teaches administering a meal enriched with amino acids, including a branched chain amino acid, along with phenylalanine and tryptophan. Additionally, Gordon does not teach suppressing abnormal prion protein proliferation by systemically, orally, intracerebrally or intraspinaly administering of an essential amino acid having branched side chain, such as leucine, isoleucine, valine and mixture thereof as recited in the present invention.

The claims are directed to suppressing abnormal prion proteins by administering of an essential amino acid having branched side chain, that is, leucine, isoleucine, valine and mixtures thereof. Because the proposed combination of references lacks any teaching or suggestion that the essential amino acids having a branched side chain of the present claims would be effective to suppress proliferation of abnormal prion proteins, the claimed invention is not rendered obvious. Further, Richardson's amino acid enriched meal is significantly different from the claimed simple treatment of administering an essential amino acid having a branched side chain.

In view of these differences between the cited references and the claimed invention, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 101551.55779US).

Respectfully submitted,

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